THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte W. SCOTT SAMSEL

Appeal No. 97-1871
Application 08/325,847[1]

ON BRIEF

Before CALVERT, STAAB and NASE, Administrative Patent Judges.

CALVERT, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal from the final rejection of claims 1 to 18 and 20 to 32, all the claims remaining in the application.

The appealed claims are reproduced in Appendix I of appellant's brief.

The subject matter in issue is exemplified by claim 1:

[1] Application for patent filed October 19, 1994.

1. A method for producing blunt tip surgical needles, comprising:

a) providing a curved surgical needle with a sharp pointed tip;

b) forming a substantially hemispherical radius on the tip of said surgical needle by a first tumbling operation in a tumbler with a first medium for a first duration of tumbling time, wherein the ratio of the radius after tumbling to the diameter of the needle ranges from about 0.15 to about 0.29.

The references applied in the final rejection are:

Schulte	1,678,359	July 24, 1928
Balz et al. (Balz)	2,318,580	May 11, 1943
Baylin	2,435,488	Feb. 3, 1948
Gillette et al. (Gillette)	2,683,343	July 13, 1954
Gleszer	2,978,850	Apr. 11, 1961
Bishop	3,239,970	Mar. 15, 1966
Kittredge et al. (Kittredge)	3,613,317	Oct. 19, 1971
Samsel et al. (Samsel)	5,447,465	Sept. 5, 1995 (filed Aug. 19, 1993)
Smith et al. (Smith)	5,477,604	Dec. 26, 1995 (filed Nov. 1, 1993)

Additional references applied herein in rejections pursuant to 37 CFR §1.196(b) are:[2]

McIntosh	5,123,910	June 23, 1992
Stametz et al. (Stametz)	5,601,475	Feb. 11, 1997 (effective filing date July 27, 1994)

The appealed claims stand finally rejected as follows:

(I.) Claims 1 to 18, 20, 21 and 30 to 32, unpatentable as being based on a specification which fails to

[2] The McIntosh patent is of record in the application; a copy of Stametz is enclosed herewith.

comply with 35 U.S.C. § 112, first paragraph.

(II.) Unpatentable under 35 U.S.C. § 103 over the following combinations of references:

(a) Claims 1 to 3, 8, 9, 20 to 22, 31 and 32, Baylin in view of Bishop and Smith;

(b) Claims 10 and 11, Baylin in view of Bishop, Smith and Kittredge;

(c) Claim 12, Baylin in view of Bishop, Smith and Gleszer;

(d) Claims 16 and 17, Baylin in view of Bishop, Smith and Schulte;

(e) Claim 18, Baylin in view of Bishop, Smith and Gillette;

(f) Claims 4 to 7, 13 to 15, 23 to 25 and 27 to 30, Baylin in view of Bishop, Smith and Balz;

(g) Claim 26, Baylin in view of Bishop, Balz and Gleszer.

(III.) Claims 1 to 18 and 20 to 32, unpatentable over claims 1 to 15 of Samsel on the ground of obviousness-type double patenting.[3]

Rejection (I)

On page 3 of the answer, the examiner states that the basis of this rejection is that "the disclosure is enabling only for claims limited to those not claiming the ratio range which is treated as new matter as noted below. See M.P.E.P. §§ 706.03(n) and 706.03(z)."[4]

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[3] A rejection of claims 1 to 18 and 20 to 32 as unpatentable over Samsel in view of Smith under 35 U.S.C. § 103 was not repeated in the answer and therefore is presumed to have been withdrawn. Ex parte Emm, 118 USPQ 180 (Bd. Apps. 1957).

[4] These Sections are not in the current (July 1998) edition of the MPEP, but are quoted in part (continued...)

The examiner does not specify what "the ratio range" is, but it appears from the final rejection and the arguments in appellant's brief and the examiner's answer that this expression is understood by appellant and the examiner to apply to three claimed ratio ranges, i.e.:

(1) the range of the ratio of the radius after tumbling to the diameter of the needle recited in claim 1, and

((2) the ranges of the ratio of the particle diameter of the second (burnishing) medium to the diameter of the surgical needle recited in claims 4 and 30.

With regard to the question of lack of enablement, on which the rejection is ostensibly based, the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification. In re Vaeck, 947 F.2d at 495, 20 USPQ2d at 1444-45. In other words, there must be sufficient disclosure to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. Id.

Whether the disclosure of species within a range is sufficient to enable one of ordinary skill to make and use subject matter within the scope of the range is dependent on the predictability of the effect of changes in the subject matter. Thus, as stated in In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970):

> In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other

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[4](...continued)
in footnotes 19 and 20 of In re Vaeck, 947 F.2d 488, 492, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). They apparently have been replaced by MPEP § 2164.08.

> embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity,
>
> the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

In the present case, Examples 2 and 3 on pages 5 to 6 of the specification disclose how to make needles having a particular tip radius and body diameter. The ratios recited in claim 1 (range (1), supra) as the end points of the claimed range are ratios calculated from the tip radius and needle diameter of the needles resulting from Examples 2 and 3, respectively. This is a case involving mechanical elements, and it appears to us that, given the disclosure in the present application, and particularly Examples 2 and 3, it would be evident to one of ordinary skill, using only routine experimentation, how to produce needles having ratios falling between the end points of the claimed range. For similar reasons, we reach the same conclusion with respect to the ranges ((2), supra) recited in claims 4 and 30. Appellant's disclosure therefore satisfies the enablement requirement of § 112, first paragraph. See National Recovery Technologies Inc., v. Magnetic Separation Systems Inc., __ F.3d__, 49 USPQ2d 1671, 1676 (Fed. Cir. 1999) ("In order to satisfy the enablement requirement of § 112, paragraph 1, the specification must enable one of ordinary skill in the art to practice the *claimed* invention without undue experimentation").

However, this does not end the inquiry under the first paragraph of § 112, because although the examiner states the basis of the rejection as lack of enablement, both he and the appellant have argued

the rejection as though the basis were a lack of written description, which is a separate statutory requirement. Thus, on pages 7 to 9 and 18 of the brief, appellant argues the rejection in terms of new matter or lack of support, both of which concern the written description requirement of § 112, first paragraph, see In re Higbee, 527 F.2d 1405, 1406 , 188 USPQ 488, 489 (CCPA 1976), and cites cases relating thereto (e.g., In re Herschler, 591 F.2d 693, 701, 200 USPQ 711, 717 (CCPA 1979), cited on page 8 of the brief). Likewise, the examiner's arguments on pages 8 and 9 of the answer concern the question of lack of support. We will therefore treat the rejection under § 112, first paragraph, as having included the ground of non-compliance with the written description requirement.

In order to comply with the written description requirement, appellant's application, as filed, "must contain sufficient disclosure, expressly or inherently, to make it clear to persons skilled in the art that appellant possessed the subject matter claimed." In re Mott, 539 F.2d 1291, 1297, 190 USPQ 536, 541 (CCPA 1976). This requirement is separate and distinct from that of enablement. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991); In re Barker, 559 F.2d 588, 593, 194 USPQ 470, 474 (Fed. Cir. 1977), cert. denied, 434 U.S. 1064 (1978). Considering first the range recited in claim 1, the end points of that range, about 0.15 to about 0.29, are inherently described in the application as filed, since they are calculable from the values given in Examples 2 and 3, respectively. However, we do not consider that this disclosure would convey to one of ordinary skill that appellant had invented a method in which the ratio range would be within the

range recited in claim 1, i.e., that one skilled in the art could derive the claimed range from appellant's disclosure. Vas-Cath Inc., 935 F.2d at 1565, 19 USPQ2d at 1119. The end points of the range are simply two values calculated from two examples, and we find no disclosure in the application as filed that the ratio of the tip radius to the needle diameter should fall between those points, or even that the radius of the tip has or should have any relationship whatsoever to the diameter of the needle. There is, therefore, nothing in the disclosure which describes the claimed range limitations "so clearly that persons of ordinary skill in the art will recognize from the disclosure that appellants invented processes including those limitations." In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976).

We reach the same conclusion with regard to the ranges of the ratio of the particle diameter of the second medium to the diameter of the surgical needle recited in claims 4 and 30. Here again, while the end points of these ranges can be calculated by picking and choosing various particle diameters and needle diameters disclosed in the specification (as demonstrated on page 18 of the brief), the application as filed does not convey that appellant was in possession of the claimed ranges as of the filing date of his application.

Rejection (I) will accordingly be sustained.

Rejections (II)(a) to (g)

On page 3 of the brief, appellant groups the claims on appeal into five groups, of which Group 1 consists of claims 1, 3, 8 to 12, 16 to 18, 20, 21, 31 and 32. Accordingly, we select claim 1 from

this group and shall decide the appeal as to the § 103 rejections of the claims of this group based thereon.

In rejecting claim 1 et al under 35 U.S.C. § 103 (rejection (II)(a)), the examiner applied Baylin in view of Bishop and Smith, citing Bishop for its disclosure of various tumbling media, and Smith for its disclosure of curved needles. It is however unnecessary to consider either Bishop or Smith with regard to claim 1, because claim 1 does not recite any particular medium, nor does it recite curved needles.

Appellant's only argument concerning Baylin, as applied to the Group 1 claims, is (brief, page 10):

> Baylin discloses the tumbling of knitting needles in order to polish them, but neither discloses nor suggests the steps of providing a needle with a sharp pointed tip and then forming a radius on the tip of the needle by tumbling. Baylin's needles are stacked in aligned parallel relationship so that the rotating and to-and-fro motion of the container causes them to rub along their sides. If, as the Office Action suggests, Baylin starts out with pointed needles, this fact does not militate against appellant's argument. The Baylin needles would be expected to keep their points for their original purpose of knitting. The tips of the Baylin needles are not disclosed as being blunted or radiused by this operation.

We do not agree with this argument. Baylin discloses tumbling the container 16 containing knitting needles and a "suitable abradant" (col. 2, lines 29 and 32). The needles to be tumbled would have sharp pointed tips, as claimed, the term "sharp" being but a relative term and applicable to the tip of a knitting needle. The examiner takes the position that the tips of Baylin's needles would inherently have radii formed on them when tumbled with an abradant; as he states on page 9 of the answer:

> A skilled artisan would realize that it is inherent that needles will be deburred or blunted or radiused when tumbled in a container with an abradant. The abradant does not discriminate between parts of the object being tumbled and any sharp edges on the needles will be blunted or "radiused".

We consider the examiner's position to be reasonable, for even if the needles are stacked in aligned relationship, as appellant asserts, the abradant would still contact their tips. Moreover, such radiusing would not prevent their use for knitting as appellant implies. Appellant has not met his burden of showing that a radius would not inherently be formed on the tips of Baylin's needles. See In re Schreiber, 128 F.3d 1473, 1478, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997).

We will therefore sustain the rejection under § 103 of claim 1, and of claims 3, 8 to 12, 16 to 18, 20, 21, 31 and 32 grouped therewith.

Appellant's Group 2 contains only claim 2, which depends on claim 1 and recites that the needle is curved. We will not sustain this rejection, because even though Smith discloses a curved surgical needle, we find nothing in Smith which would suggest curving the knitting needles disclosed by Baylin, which are used for an entirely different purpose. We likewise will not sustain the rejections of claims 22 to 30 (appellant's Groups 4 and 5), all of which call for curved needles.

Finally, the claims in appellant's Group 3, Claims 4 to 7 and 13 to 15, all are dependent on claim 4 and therefore include the recitations of claim 4 that "the second medium comprises particles having a hardness greater than that of the needles [sic: needle] and having no surface feature with a radius less than the diameter of the needle." We find no disclosure in any of the applied references,

particularly Balz, which would teach or suggest these limitations, and will not sustain the rejection of claims 4 to 7 and 13 to 15 under § 103.

Rejection (III)

The examiner states in the answer as to this rejection (pages 7 and 8):

> The patented and the pending claims set forth the same invention of substantially the same scope except the invention of patented claims 1-15 contain needle size and particle size limitations. However, it is well known in the art that the size of the tumbling media and the size of the articles being tumbled can be varied and are strictly choices of the operator.
>
> It would have been obvious to one of ordinary skill in the art to have utilized the process of claims 1-5 without specific limitations on the tumbling media or the articles being tumbled.

The only argument we find in appellant's brief concerning this rejection is on page 15 (original emphasis):

> Reversal of this rejection is respectfully requested. Samsel et al. claims a process for deburring reducing the sharp edges of needle blanks. There is no suggestion in the Samsel et al. claims to radius the tip of an already sharply pointed needle to provide a blunt tip having the recited radius. Accordingly, it is respectfully submitted that the claims in the present application are not obvious over the claims in the Samsel et al. '465 patent.

The examiner responds at page 11 of the answer:

> Appellant correctly states that the Samsel et al. reference claims a method for deburring and reducing sharp edges of needle blanks. However, it is offered that "deburring and reducing sharp edges" is essentially the same thing as forming a substantially hemispherical radius tip because the tip before Appellant's method is a sharp edge and it is reduced. Further, it is offered that the treatment of needle blanks and the treatment of needles are substantially the same scope. The Samsel et al. claims

suggest that sharp edges along the entire needle are subject to "radiusing" or reduction.

We consider the examiner's position to be correct. There would appear to be little practical difference between the "needles" recited in appellant's claims and the "needle blanks" recited in the claims of the Samsel patent, and in particular, the "polished needle blanks" recited in claims 5 to 15 of the patent. Moreover, claims 22 to 30 only claim the treatment of "partially finished" needles. For the reasons stated by the examiner, supra, this rejection will be sustained.

Rejections Pursuant to 37 CFR § 1.196(b)

Pursuant to 37 CFR § 1.196(b), we enter the following new grounds of rejection.

(a) Claims 1 to 3, 8 to 11, 16, 20, 21, 31 and 32 are rejected under 35 U.S.C. § 103 as unpatentable over Stametz in view of McIntosh. Stametz discloses a method of producing blunt tip surgical needles (including curved needles) by tumbling sharp, tapered tip needles 10 with an abrasive 40. The abrasive may include a liquid (col. 2, line 48), the abrasive medium may be porcelain, etc., spheres (col. 5, lines 11 to 21), and the needles may be 420 stainless steel (col. 5, line 37). As for the ratio range recited in claim 1, McIntosh teaches that blunt surgical needles should have a percentage of bluntness (diameter of curvature) of 25 to 62% of the diameter of the needle (col. 9, lines 12 to 19). This is the same as a ratio of tip radius to needle diameter of 0.125 to 0.31, which embraces the range recited in claim 1. Also, McIntosh teaches the use of needle diameters of 0.026 to 0.050 inches and tip

radii of 0.003 to 0.0155 inches (0.006 to 0.031 inches in diameter) (col. 9, lines 23 to 26). In view of this disclosure, it would have been obvious to one of ordinary skill in the art to use the Stametz process to produce needles having the ratios, tip radii (diameters) and shaft diameters taught by McIntosh as being desirable for blunt surgical needles.

(b) Claim 22 is rejected under 35 U.S.C. § 102(e) as being anticipated by Stametz. Note Stametz' disclosure that the needles being tumbled may be "semi-finished" and have tapered tips (col. 4, lines 7 to 10).

We note that since appellant is claiming the same invention as at least claim 1 of the Stametz patent, it cannot be overcome via an affidavit or declaration under 37 CFR § 1.131.

See MPEP § 715.05.

Remand to the Examiner

This application is remanded to the examiner to determine whether claims 4 to 7, 12 to 15, 17, 18 and 23 to 30 should be rejected under § 103 as unpatentable over Stametz in view of other prior art.

Conclusion

The examiner's decision to reject claims 1 to 18, 20, 21 and 30 to 32 under 35 U.S.C. § 112, first paragraph, and to reject claims 1 to 18 and 20 to 32 on the ground of obviousness-type double patenting, is affirmed. The examiner's decision to reject claims 1 to 18 and 20 to 32 under 35

U.S.C. § 103 is affirmed as to claims 1, 3, 8 to 12, 16 to 18, 20, 21, 31 and 32, and is reversed as to claims 2, 4 to 7, 13 to 15 and 22 to 30. Claims 1 to 3, 8 to 11, 16, 20 to 22, 31 and 32 are rejected pursuant to 37 CFR § 1.196(b), and the application is remanded to the examiner.

In addition to affirming the examiner's rejections of one or more claims, this decision contains new grounds of rejection pursuant to 37 CFR § 1.196(b)(amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196(b) provides, "A new ground of rejection shall not be considered final for purposes of judicial review."

Regarding any affirmed rejection, 37 CFR § 1.197(b) provides:

> (b) Appellant may file a single request for rehearing within two months from the date of the original decision . . . .

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new grounds of rejection to avoid termination of proceedings (37 CFR § 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
>
> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

Should the appellant elect to prosecute further before the Primary Examiner pursuant to 37 CFR § 1.196(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejections, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejections are overcome.

If the appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejections, including any timely request for rehearing thereof.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED; 37 CFR § 1.196(b);
REMANDED

IAN A. CALVERT)
Administrative Patent Judge)
)
)
) BOARD OF PATENT

LAWRENCE J. STAAB	)	
Administrative Patent Judge	)	APPEALS AND
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Appeal No. 97-1871
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